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JAN - 5 2011

K103618

510(k) Summary

TurboHawk™ Peripheral Plaque Excision System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson Principal Regulatory Affairs Specialist
Date Prepared	December 3, 2010

2. Subject Device

Device Trade Name	TurboHawk™ Peripheral Plaque Excision System
Device Common Name	Catheter, Peripheral, Atherectomy
Classification Name	Intraluminal Artery Stripper 21 CFR 870.4875, Product Code MCW
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	TurboHawk™ Peripheral Plaque Excision System; SilverHawk™ Peripheral Plaque Excision System
510(k) Number	K093301; K061188
510(k) Clearance Date	November 6, 2009; October 23, 2006

4. Device Description

The TurboHawk Peripheral Plaque Excision System (TurboHawk Catheter and ev3 Cutter Driver) is designed for the treatment of de novo and restenotic calcified and non-calcified atherosclerotic lesions located in native peripheral arteries. The TurboHawk Catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the TurboHawk Catheter is a small cutting assembly comprised of a rotating inner cutter contained within a

tubular housing. The proximal end of the TurboHawk Catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the ev3 Cutter Driver. The ev3 Cutter Driver is a handheld, disposable, battery-driven unit (Catalog No: 02550) which powers the system.

The TurboHawk Peripheral Plaque Excision System has two switches: 1) the SilverHawk Cutter Driver main power switch and 2) the TurboHawk Catheter thumb switch. The ev3 Cutter Driver main power switch supplies power to the device when turned ON. The TurboHawk Catheter thumb switch activates the drive shaft and engages the cutter when pulled proximally to the ON position. With the cutter engaged, the TurboHawk Catheter is slowly advanced across the lesion, shaving occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the TurboHawk Catheter thumb switch distally deactivating the drive shaft and disengaging the cutter. The TurboHawk Catheter thumb switch is fully advanced distally to the OFF position in order to pack the excised plaque into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.

5. Indications for Use

The TurboHawk Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The TurboHawk Catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

6. Comparison of Technological Characteristics

The TurboHawk Peripheral Plaque Excision System has the following similarities to the predicate device:

- Identical indications for use
- Identical intended use as the predicate TurboHawk Peripheral Plaque Excision System
- Similar fundamental scientific technology
- Similar operating principle
- Similar materials

7. Performance Testing Summary

To demonstrate substantial equivalence of the subject device, the TurboHawk Peripheral Plaque Excision System to the predicate device, the technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Analysis procedures, the following in vitro tests were performed:

- Effective length
- Guidewire loading
- Cutter height
- Cycle and life
- Carbide edge attachment
- Proximal drive shaft joint torque test
- Distal drive shaft assembly torque test
- Distal drive shaft assembly tensile test
- Tip, hinge, and distal torque shaft joints tensile test
- Cutter stop tensile
- Trackability
- Cut depth

- Cut mass per pass
- Guidewire lumen zip
- Embolization
- Tissue removal cycles

Testing leveraged from the predicate TurboHawk Device included spin percentage, biocompatibility, packaging and sterilization. Test results met the specified acceptance criteria and were included in K093301.

The results from these tests demonstrate that the technological characteristics and performance criteria of the TurboHawk Peripheral Plaque Excision System are comparable to the predicate device and that the TurboHawk Peripheral Plaque Excision System performs in a manner equivalent to the predicate device currently on the market for the same intended use.

8. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, ev3 considers the TurboHawk Peripheral Plaque Excision System to be substantially equivalent to the predicate TurboHawk Peripheral Plaque Excision System (K093301) and the predicate SilverHawk Peripheral Plaque Excision System (K061188).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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ev3, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K103618
Trade/Device Name: TurboHawk Peripheral Plaque Excision System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: December 9, 2010
Received: December 10, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K103618

Device Name: TurboHawk Peripheral Plaque Excision System

Indications for Use:

The TurboHawk Peripheral Plaque Excision System is intended for use in atherectomy of the peripheral vasculature. The TurboHawk Catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vaclavik

(Division Sign-Off)
Division of Cardiovascular Devices

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